



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 22 2021

ADMINISTRATIVE ORDER

No. 2021 - 0051

SUBJECT: Guidelines on Graphic Health Warnings on Vapor Products, Heated Tobacco Products and Other Similar Products

I. RATIONALE

In the 2015 Global Adult Tobacco Survey in the Philippines, the overall prevalence of ever use and current use of electronic cigarettes among all adults is at 2.8% and 0.8% respectively, with higher prevalence of electronic cigarette use among men and those living in urban areas. Among adolescents aged 13-15 years, the 2019 Global Youth Tobacco Survey shows a more alarming 14.1% of students who are currently electronic cigarette users. While the negative effects of vapor products and heated tobacco products (HTPs) are not yet fully known, evidence of their potential and long-term harmful effects are accumulating and evolving to include increased nicotine addiction, fatal respiratory problems, mucosa, poisoning, among others. Injuries from explosion have also occurred world-wide.

In relation to these emerging adverse health effects, a decision was adopted in 2014 by the Conference of Parties (COP) to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) which states that vapor products are harmful, and that sale and marketing of vapor products should be prohibited or regulated. For HTPs, an FCTC/COP decision was again adopted in 2018 which recognizes novel or emerging tobacco products, including HTPs, as tobacco products and therefore subject to the provisions of the FCTC.

Consistent with the WHO-FCTC's decisions and recommendations as well as the policy of the state to protect and promote the right to health of the people and instill health consciousness as enshrined in the 1987 Philippine Constitution, the use of vapor, HTPs, and other similar products or devices are regulated by the Department of Health (DOH) and the Food and Drug Administration (FDA) pursuant to Republic Act Nos. 11346 and 11467; and Executive Order No. 106, series of 2020.

RA No. 11346 and its Implementing Rules and Regulations, through Joint Memorandum Circular (JMC) No. 003-2020, mandated the DOH to issue guidelines on the effective implementation of the application of graphic health warnings (GHW) on the packaging of vapor products, HTPs, and other similar products compliant with RA No. 10643 or the "Graphic Health Warnings (GHW) Law". This expansion in the application of GHW seeks to effectively inform and educate the public regarding some of the health risks and dangers associated with the use of vapor products, HTPs, and other novel or similar products or devices.

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II. OBJECTIVES

This Order aims to provide guidelines on the placement and use of GHWs on vapor products, heated tobacco products (HTPs), and other similar products, and define the roles and responsibilities of the DOH, FDA, and other relevant agencies, offices, and stakeholders of vapor products, HTPs, and other similar products.

III. SCOPE OF APPLICATION

This Order shall apply to all manufacturers, importers, distributors of vapor products, HTPs and other similar products. It shall also cover all the DOH Central Office Bureaus and Services, Centers for Health Development (CHDs), including the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) subject to the applicable provisions of RA 11054 or the "Bangsamoro Organic Act" and subsequent rules and policies issued by the Bangsamoro government.

IV. DEFINITION OF TERMS

The following terminologies are operationally defined consistent with the definitions provided for by the following laws and policies: RA No. 10643 or "The Graphic Health Warnings Law," RA No. 9711 or the "Food and Drug Administration Act of 2009," RA Nos. 11346 and 11467; DOF-DOH-DBM-BIR-PhilHealth Joint Memorandum Circular No. 003-2020; EO No. 106 series 2020; DOH AO No. 2020-0055 "Regulation on Vapor Products and Heated Tobacco Products (HTPs) under the Food and Drug Administration (FDA)."

- A. **Container** - refers to any object used for or capable of holding one or more vapor products or HTPs packaging or wrapping.
- B. **Graphic Health Warnings (GHW)** - refer to the photographic image printed on the product package, which accurately depicts the hazards of use of or exposure to a product, and is accompanied by a textual warning related to the picture.
- C. **Heated Tobacco Products (HTPs)** - refer to tobacco products that may be consumed through heating tobacco, either electrically or through other means sufficiently to release an aerosol that can be inhaled without burning or any combustion of the tobacco. HTPs include liquid solutions and gels that are part of the product and are heated to generate an aerosol.
- D. **Insert** - refers to any communication inside an individual package and/or carton purchased at either wholesale or retail by consumers, such as a leaflet or brochure.
- E. **Misleading Descriptors** - refers to any element or feature, whether or not part of the brand name, which includes but is not limited to any number or descriptor, or other sign, mark, or term such as but limited to "low tar," "ultra lite," "clean," "fine," "leading," "supreme," "mild," "extra," "ultra," and similar terms in any language that directly or indirectly creates the false impression or claims or misleads a consumer to believe that the particular product is healthier, safer, or less harmful than others; or that it can be used as tobacco cessation aids or other terms in any language, that are likely to mislead consumers or suggests that the product has lifestyle or health benefits.

- F. **Novel Tobacco Products** - refer to all substances, devices, and innovations entirely or partly made of tobacco plant as raw material, already existing or to be developed in the future that are intended for use as substitutes for cigarettes, conventional tobacco products, vapor products, or HTPs.
- G. **Onsert** - refers to any communication affixed to the outside of an individual package and/or carton purchased at either wholesale or retail by consumers, such as a brochure beneath the outer cellophane wrapping or glued to the outside of the package.
- H. **Other similar products** - refers to novel and/or emerging nicotine, vapor, and tobacco product which may differ in some aspects or design but which either have the same functionality, or expose users to similar health hazards or whose components are similarly addictive and toxic or which share the same delivery mechanisms as that of vapor and HTPs. Other similar products shall adopt the corresponding GHW for vapor products or HTPs, whichever they are most similar to.
- I. **Packaging** - refers to bottles, packs, boxes, cartons, or containers of any kind used on vapor products or HTPs being offered for sale to consumers.
- J. **Primary Packaging** - refers to any material, including printed material, employed on the packaging of the product, excluding any outer packaging used for transport or shipment, that is in direct contact with the vapor product or HTP device, cartridges, and/or refills:
1. In the case of devices, mods, pods, and/or cartridges: the packs, boxes, cartons, containers or packaging of any kind; and
 2. In the case of vape or HTP juice and/or refills: the juice or refill bottles.
- K. **Principal Display Surface** - refers to "Principal Display Area or Principal Display Panel" that is predominantly displayed or visible under normal or customary conditions where the GHWs are visibly shown:
1. In the case of a package and carton that has at least two (2) equal sides or surfaces, other than the top and bottom, that may be displayed or visible under normal or customary conditions of sale or use: the areas of each of the two (2) largest surfaces.
 2. In the case of a spherical, cylindrical or conical container: the two (2) largest surfaces that are predominantly displayed.
 3. In the case of a package and carton that does not have a particular side or surface that is predominantly displayed or visible under normal or customary conditions of sale or use or those that are not described under subsections 1 and 2: fifty percent (50%) of the three (3) dominant sides or the total surface thereof, whichever is bigger, which will ensure that the GHW are visibly shown.
 4. In the case of vape or HTP juice bottles or cylindrical packages with caps:
 - a. the areas below the cap, provided that the cap is not used for advertising or promotion purposes including but not limited to the use of brand colors or the provision of brand information; or
 - b. the areas from the tip of the cap to the bottom of the bottle, provided that the cap is used for advertising or promotion purposes.

- L. **Secondary Packaging** - refers to any material, including printed material, employed on the packaging of the product, excluding any outer packaging used for transport or shipment, that is **not** in direct contact with the vapor product or HTP device, cartridges, and/or refills (e.g. product inserts, tags, etc.):
1. In the case of devices, mods, pods, and/or cartridges: any additional packaging, if any; and
 2. In the case of vape or HTP juice and/or refills: the packs, boxes, cartons, containers or packaging of any kind.
- M. **Side Panel** - refers to the surface of the package that has the largest surface available next to the principal display surface where GHWs shall appear. This is in addition to any fiscal markings as may be required by FDA, BIR, other government agencies.
- N. **Vapor Products** - refer to electronic nicotine and non-nicotine delivery systems (ENDS/ENNDS), which are a combination of (i) a liquid solution or gel, that transforms into an aerosol without combustion through the employment of a mechanical or electronic heating element, battery or circuit that can be used to heat such solution or gel and includes but not limited to (ii) a cartridge, (iii) a tank, and (iv) the device without the cartridge or tank. It is commonly known as nicotine salt/salt nicotine, and conventional 'freebase' or classic nicotine, and other similar products.

V. GENERAL GUIDELINES

- A. The DOH shall issue a maximum of twelve (12) templates of GHWs for vapor products and for HTPs and other similar products upon the approval of this Order and shall issue new templates every two (2) years thereafter to be used by all manufacturers, importers, and distributors of said products that are introduced in the Philippine market.
- B. The twelve (12) templates of GHWs shall be printed simultaneously and shall be rotated periodically for each brand family and for each variant, so that every two (2) years, the variations of the warnings shall appear in the market with approximately equal frequency and equal display of health warnings and messages on retail packages.
- C. The GHWs, in addition to other product information required by FDA pursuant to RA No. 9711 such as but not limited to warnings, product contents, direction for use, disposal, maintenance, first aid instructions, and information for traceability, shall be placed on the packaging, whether primary or secondary, including insert or onsert.
- D. The GHWs on vapor products, HTPs, and other similar products packages shall be printed in accordance with the product guide in the **Annex I** of this Order, without prejudice to subsequent or additional warnings, such as those in accordance with the Globally Harmonized System of Classification and Labelling Chemicals, or updates to policies that may be issued by the DOH or FDA in accordance with relevant laws such as RA No. 9711.

- E. The composite images of the GHWs shall be contained in a digital storage device and/or an electronic repository which shall be maintained by the DOH.
- F. All vapor products, HTPs and other similar product packages not compliant shall be subject to removal and/or confiscation by appropriate authorities and shall not be allowed to be sold or distributed in the Philippine market.

VI. SPECIFIC GUIDELINES

A. Size

- 1. The GHWs shall be printed on fifty percent (50%) of the principal display surfaces of any vapor products, HTPs, and other similar product packages, whether primary or secondary.
- 2. It shall occupy fifty percent (50%) of the front and fifty percent (50%) of the back panel.

B. Position. The GHWs shall be located at the lower portions of the panels or principal display areas.

C. Visibility

- 1. No part of the warning shall be obliterated, obscured, folded, severed or become unreadable when a wrapper or sleeve on the package is removed.
- 2. Nothing shall be printed or applied on a location where it is likely to obscure or cover in part or in whole the GHWs.

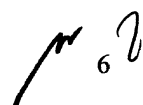
D. Color and Printing Quality

- 1. The GHWs shall be printed in four colors /-cmyk-/ screen 133 lines per inch based on a source file of 300 dpi.
- 2. The printing of the GHWs shall be done using current available technology for purposes of providing vivid and realistic pictures. The primary consideration in determining the printing quality shall be the overall effect on the vapor products, HTPs, and other similar products packaging.
- 3. The printing shall be clear and legible throughout the lifecycle of the product, under normal or customary conditions of transportation, storage, sale and use.
- 4. The GHWs shall be as clear, vivid and vibrant as the rest of the packaging. Any ink used in the printing of the GHWs shall be of such a quality that will not fade, bleed, or modify the appearance of the warning over time.
- 5. The printing shall not include any features designed to modify the warnings, including, but not limited to heat activated inks, inks or embellishments designed to appear gradually over time, or inks that appear fluorescent in certain light.
- 6. The printing of the GHWs shall be done without the use of any border, frame, cropping, distortion or any other design that will effectively lessen the size of the warning, reduce its clarity and vividness, or modify the appearance.
- 7. The GHWs shall be printed or inscribed on the package in a color which contrasts conspicuously with the background of the package or its labels, as provided by these guidelines and templates.
- 8. The GHWs shall be reproduced in the same quality, color and proportion as provided by the DOH in the templates or in the digital form, whichever is clearer and more vivid, without modification.

- E. **Language.** The text warning accompanying the photographic image shall be printed in Filipino on the front panel and English on the back panel. In the case of other containers where there is only one (1) external surface area, the accompanying text shall be printed alternately in English or Filipino.
- F. **Side Panel.** Vapor products, HTPs, and other similar products packages found in the market, shall bear, on one (1) side panel, additional health warnings, hotlines and/or websites on cessation, which shall be prominently displayed without the use of any border, frame or any other design that will effectively lessen the size of the textual warning, in accordance with the templates provided. Such information shall occupy thirty percent (30%) of the display surface of one side panel.
- G. **Misleading Descriptors**
1. Vapor products, HTPs, and other similar product packages shall not bear any number or descriptor, or other sign, mark, or term such as but limited to “low tar,” “ultra lite,” “clean,” “fine,” “leading,” “supreme,” “mild,” “extra,” “ultra,” and similar terms in any language that claims or misleads a consumer to believe that the vapor products, HTPs, and other similar products or variant is healthier, safer, less harmful or approved for use as a smoking cessation device, unless otherwise approved for such use by the FDA.
 2. The DOH shall not approve any proposal, proof or other submission of GHWs that is affixed to vapor products, HTPs, and other similar products packages that bear any such number or descriptor.

VII. ROLES AND RESPONSIBILITIES

- A. The **Health Promotion Bureau (HPB)** shall:
1. Develop the GHW templates on vapor products, HTPs, and other similar products; and oversee its dissemination, implementation, monitoring and evaluation;
 2. Develop health promotion and communication plans on health effects of vapor products, HTPs and other similar products, including capacity building and health education in schools, workplaces, and communities;
 3. Maintain a digital storage device and/or an electronic repository of the GHWs on vapor products, HTPs and other similar products; and
 4. Coordinate and provide technical assistance to public health advocates, professional and civil societies, and various relevant stakeholders in relation to GHW on vapor products, HTPs and other similar products.
- B. The **Food and Drug Administration (FDA)** shall oversee the regulation and ensure application of GHW as well as other health warnings or information on the ingredients or contents of the vapor products, HTPs and other similar products.
- C. The **Epidemiology Bureau (EB)** shall include in the conduct of Global Tobacco Surveillance System relevant information on vapor products, HTPs and other similar products such as but not limited to: prevalence of use, access by minors, placement of GHW, and advertisement and promotions.
- D. The **Bureau of International Health Cooperation (BIHC)** shall collaborate with International Organizations such as but not limited to World Health Organization



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and Member States, to further strengthen the capacity in the implementation of this Order.

- E. The **DOH Hospitals and other health facilities** shall promote cessation of the use of vapor products, HTPs and other similar products in all levels of care.
- F. The **DOH Centers for Health Development** and the **Ministry of Health-BARMM** shall:
 - 1. Orient concerned stakeholders on the policy and advocate for its adoption and implementation; and
 - 2. Provide technical assistance to Local Government Units and other partners on health effects of vapor use, HTPs, and other similar products.
- G. The **Local Government Units**, including Provincial and District Hospitals, are enjoined to promote the cessation of use of vapor products, HTPs and other similar products in all levels of care.

VIII. TRANSITORY PERIOD

All manufacturers, importers, distributors and sellers of vapor products, heated tobacco products, and other similar products shall comply with the guidelines set out in this Order in a timeline consistent with Rule III, Section 3 of the DOF-DOH-DBM-BIR-PHIC Joint Memorandum Circular No. 003-2020 or the “Implementing Rules and Regulations of Heated Tobacco Products and Vapor Products as Prescribed by RA Nos. 11346 and 11467.”

In this regard, all manufacturers and importers of vapor products, heated tobacco products, and other similar products shall comply with the requirements of this Order and shall apply the first (1st) set of GHW templates for vapor products, heated tobacco products, and other similar products in full effect by **May 11, 2022**.

All distributors and sellers of vapor products, heated tobacco products, and other similar products shall be provided with additional sixty (60) days or until **July 11, 2022** to fully comply with the same.

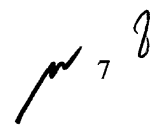
Thereafter, no person or legal entity shall sell or commercially distribute or display any vapor product, heated tobacco product, and other similar product without ensuring that the packages meet the standards under this Order. Manufacturers, importers, distributors and sellers shall ensure the removal from all displays of non-compliant products.

IX. PENALTY CLAUSE

Violations and non-compliance of this Order shall be subject to existing penalties and sanctions in RA No. 10643 or the “The Graphic Health Warnings Law” and relevant laws as applicable.

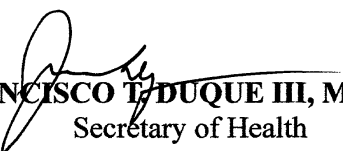
X. SEPARABILITY CLAUSE

If any provision of this Order is declared invalid, unenforceable or unconstitutional, the validity or enforceability of the remaining provisions shall not be affected, and this Order shall be interpreted as if it did not contain the particular invalid, unenforceable, or unconstitutional provision.

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XI. EFFECTIVITY

This Order shall take effect immediately after publication in the Official Gazette or a newspaper of general circulation and submission to the Office of the National Administrative Registry (ONAR) at the UP Law Center.



FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX I. Product Guide

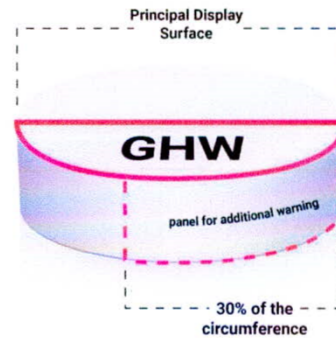
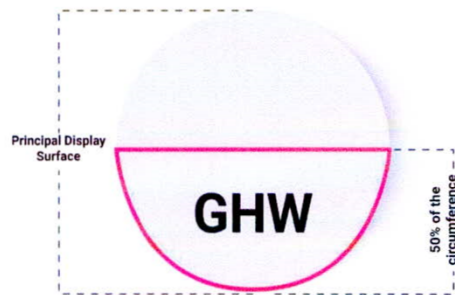
A. Summary of packaging requirement by product component

Packaging	Product Components	
	Devices/Mods/Pods/Cartridges	Juice/Refill Bottles
Primary	Packs, boxes, cartons, containers or packaging of any kind <i>with GHW</i>	Juice/Refill bottle <i>with GHW</i>
Secondary	Additional packaging (if any) <i>with GHW</i>	Packs, boxes, cartons, containers or packaging of any kind <i>with GHW</i>

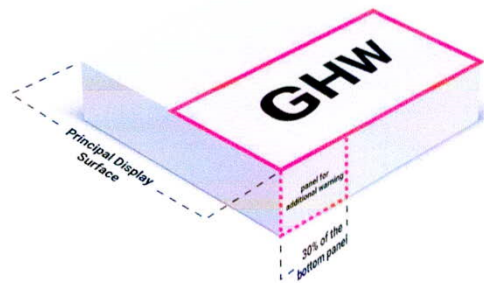
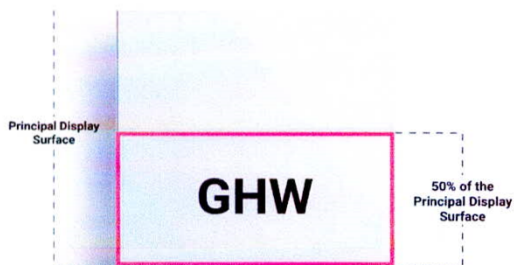
B. Summary of GHW application for round or disc-type packaging, wide box packaging, and standard box packaging:

GHW Size	<ul style="list-style-type: none"> 50% of the principal display surface both front and back
GHW Position	<ul style="list-style-type: none"> Lower portion of the principal display surface
GHW Visibility	<ul style="list-style-type: none"> GHW shall not be obscured or covered
GHW Color and Printing Quality	<ul style="list-style-type: none"> Four colors /-cmyk-/ screen 133 lines per inch source file of 300 dpi GHW shall be clear, legible, vivid and vibrant. GHW shall not fade, bleed, or modify the appearance of the warning over time. No features designed to modify the warnings overtime No border, frame, cropping, distortion or any other design that will lessen the size of the GHW.
GHW Language	<ul style="list-style-type: none"> Filipino on the front panel; English on the back panel
Side Panel	<ul style="list-style-type: none"> Additional health warnings, hotlines, and/or websites on cessation Occupying 30% of the display surface of one side panel
Misleading Descriptors	<ul style="list-style-type: none"> Shall not bear any misleading descriptors or claims

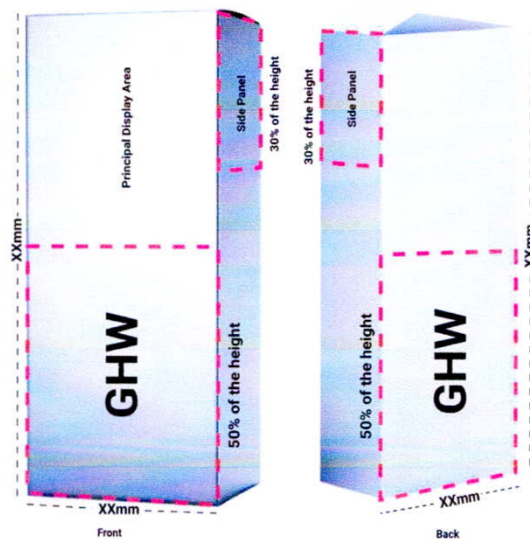
Round or Disc-Type Packaging



Wide Box Packaging

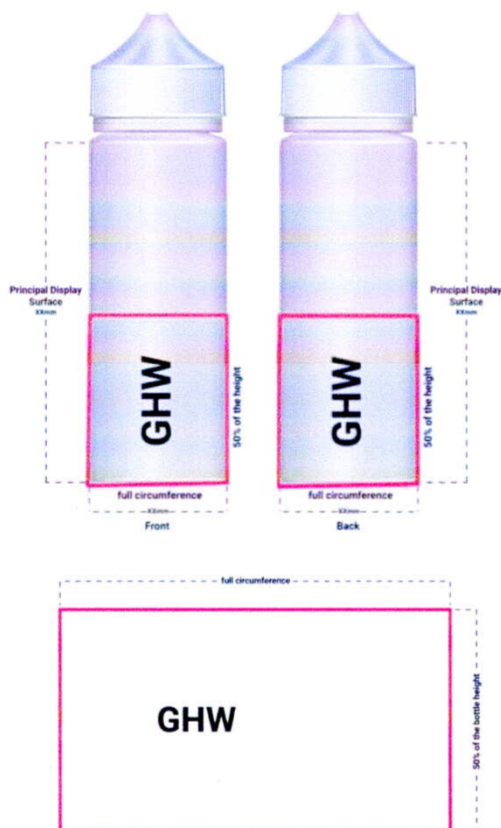


Standard Box Packaging



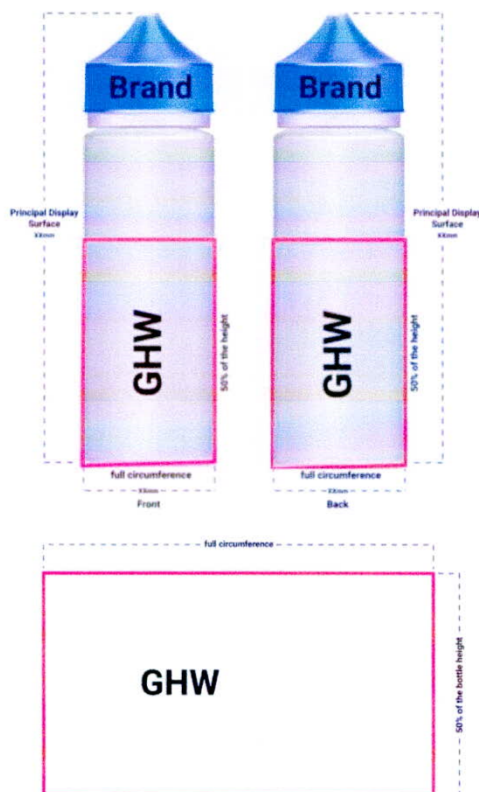
C. GHW application for vape and HTP juice or refill bottles

- i. For bottles with caps that are NOT used for advertising or promotion purposes, including but not limited to the use of brand colors or the provision of brand information; Prescribed color include: plain black, white, brown



GHW Size	<ul style="list-style-type: none"> 50% of the principal display surface of the full circumference of the bottle with measurement of the height starting from below the cap
GHW Position	<ul style="list-style-type: none"> Lower portion of the principal display surface
GHW Visibility	<ul style="list-style-type: none"> GHW shall not be obscured or covered
GHW Color and Printing Quality	<ul style="list-style-type: none"> Four colors /-cmyk-/ screen 133 lines per inch source file of 300 dpi GHW shall be clear, legible, vivid and vibrant. GHW shall not fade, bleed, or modify the appearance of the warning over time. No features designed to modify the warnings overtime No border, frame, cropping, distortion or any other design that will lessen the size of the GHW.
GHW Language	<ul style="list-style-type: none"> Either in Filipino or English
Misleading Descriptors	<ul style="list-style-type: none"> Shall not bear any misleading descriptors or claims

- ii. For bottles with caps colored other than with plain black, white, or brown, and are used for advertising or promotion purposes, including but not limited to the use of brand colors or the provision of brand information



GHW Size	<ul style="list-style-type: none"> 50% of the principal display surface of the full circumference of the bottle with measurement of the height starting from the tip of the cap
GHW Position	<ul style="list-style-type: none"> Lower portion of the principal display surface
GHW Visibility	<ul style="list-style-type: none"> GHW shall not be obscured or covered
GHW Color and Printing Quality	<ul style="list-style-type: none"> Four colors /-cmyk-/ screen 133 lines per inch source file of 300 dpi GHW shall be clear, legible, vivid and vibrant. GHW shall not fade, bleed, or modify the appearance of the warning over time. No features designed to modify the warnings overtime No border, frame, cropping, distortion or any other design that will lessen the size of the GHW.
GHW Language	<ul style="list-style-type: none"> Either in Filipino or English
Misleading Descriptors	<ul style="list-style-type: none"> Shall not bear any misleading descriptors or claims